

Attorney Docket No.: INT-0004
Inventors: Mattern et al.
Serial No.: 10/002,653
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This listing of the claims will replace all prior versions
and listings of claims in the application:

Listing of the claims:

Claim 1: (canceled)

Claim 2: (currently amended) The composition of claim 1 scaffold
or matrix of claim 13 further comprising a silicone layer applied
to the collagen and glycosaminoglycan co-precipitate prior to
cross-linking.

Claim 3: (currently amended) A terminally sterilized matrix or
scaffold comprising the composition of claim 1 scaffold or matrix
of claim 13 terminally sterilized by electron beam irradiation.

Claim 4: (currently amended) A terminally sterilized matrix or
scaffold comprising the composition scaffold or matrix of claim 2
terminally sterilized by electron beam irradiation.

Claim 5: (currently amended) A method for producing the
composition of claim 1 scaffold or matrix of claim 13 comprising
cross-linking the collagen and glycosaminoglycan co-precipitate
with glutaraldehyde at a density of cross-linkage which

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stabilizes the composition scaffold or matrix toward electron beam radiation at about 15 to about 80 kGy while retaining characteristics of the composition to function as a so that the matrix or scaffold retains characteristics to function as a structural support for cell and to support tissue ingrowth.

Claim 6: (currently amended) The method of claim 5 wherein cross-linking of the composition collagen and glycosaminoglycan co-precipitate is performed with glutaraldehyde at a concentration greater than 0.25%.

Claim 7: (currently amended) The method of claim 5 wherein the composition collagen and glycosaminoglycan co-precipitate is subjected to two or more glutaraldehyde cross-linking steps.

Claim 8: (original) The method of claim 7 wherein the two or more cross-linking steps are performed with glutaraldehyde at 0.25%.

Claim 9: (currently amended) A method for producing a terminally sterilized matrix or scaffold comprising:

(a) producing a composition of claim 1 scaffold or matrix of claim 13;

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(b) sealing the composition in a package; and
(c) exposing the composition in the sealed package to
electron beam radiation.

Claim 10: (canceled)

Claim 11: (original) A terminally sterilized matrix or scaffold produced in accordance with the method of claim 9.

Claim 12: (original) A method for regenerating dermal or sub-dermal tissue in a subject comprising applying to or implanting within the subject the terminally sterilized matrix or scaffold of claim 3 at or near an excision site of dermal or subdermal tissue or a site where augmentation of dermal or subdermal tissue is required.

Claim 13: (currently amended) A ~~composition scaffold or matrix~~ comprising a collagen and glycosaminoglycan ~~co-precipitate~~ cross-linked ~~with glutaraldehyde~~ at a density ~~of cross-linkage~~ which stabilizes the ~~composition scaffold or matrix~~ toward electron beam radiation ~~at about 15 to about 80 kGy while retaining characteristics of the composition to function as a~~ so that the

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matrix or scaffold retains characteristics to function as a
structural support for cell and to support tissue ingrowth.